REMARKS

Favorable reconsideration of this application is requested in view of the following remarks.

Claim 1 has been canceled without prejudice. Claim 2 has been amended editorially and further amended as supported by the specification at page 5, lines 1-20 and page 6, lines 7-12. Claim 3 has been amended editorially and further amended as supported by the specification at page 5, line 21-29. Claims 4-13 and 15-17 and withdrawn claim 14 have been amended editorially.

Claims 1-13 and 15-17 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Claim 1 has been canceled, and base claim 2 has been amended to clarify that the claim includes a step of mixing the liquid sample with a protein measurement indicator and forming the first liquid system, a step of obtaining a first response value based on coloring of the protein measurement indicator caused by reactions between the indicator and protein and between the indicator and creatinine in the first liquid system, a step of preparing a second liquid sample as a second liquid system, a step of obtaining a second response value that reflects a creatinine concentration in the second liquid system, and a step of calculating a protein concentration in the liquid sample by using the first and second response values for eliminating the measurement error caused by the reaction between the indicator and creatinine. Accordingly, claim 2 is clear and well defined, and this rejection should be withdrawn.

Claims 1, 2-9, 11-13, and 15-17 have been rejected under 35 U.S.C. 112, second paragraph, as being incomplete. Applicants respectfully traverse this rejection.

Claim 1 has been canceled, and base claim 2 includes steps, particularly, the step of obtaining a first response value of the first liquid system, the step of obtaining a second response value, and the step of calculating a protein concentration in the liquid sample as discussed above. From the step of obtaining a first response value and the step

of calculating a protein concentration in the liquid sample, it is clear that creatinine reacts with the protein measurement indicator and causes a measurement error, which is included in the first response value, in addition to the reaction between the indicator and protein in the first liquid system. In the step of obtaining the second response value, the method to determine a creatinine concentration is limited to methods that do not includes the protein measurement indicator. Further, in the step of calculating a protein concentration in the liquid sample, the measurement error caused by the reaction between creatinine and the indicator is eliminated by using the first and second response values.

In addition, claim 2 is clear about the coloring, which is based on the coloring of the protein measurement indicator caused by a reaction between the protein and the indicator and a reaction between creatinine and the indicator as recited in the step of obtaining a first response value.

Claim 5 clearly indicates that the corrected response value is the corrected response value of the first response value.

Claim 9 is directed to a method of preparing the calibration curve, and it is clear that the response values of the known liquid samples obtained by the two protein measurement procedures are used for preparing the calibration curve, which is prepared before being used for the step of calculating the protein concentration in the liquid sample. It is also clear in claim 9 that the relationship is between the responses of known liquid samples obtained by the first protein measurement procedure, i.e., the responses of protein and creatinine in the known liquid samples, and the protein concentrations of the known liquid samples obtained by the second protein measurement procedure, which is less susceptible to creatinine than the first protein measurement procedure, i.e., responses of protein in the known liquid samples with less influence of creatinine is obtained by the second protein measurement procedure.

Accordingly, claim 2 and claims 3-9, 11-13, and 15-17 include all steps and are complete claims, and this rejection should be withdrawn.

Claim 2 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Applicants note that this rejection has been placed in the discussion of the incompleteness rejection above (see item 9 on page 4 of the Office Action). Applicants, however, assume that this indefiniteness rejection is a separate rejection and discussed separately herein.

Claim 2 has been amended to remove the term "in consideration of" (previously misspelled as "inconsideration of") and clarify that in addition to the first response value, the second response value is used for eliminating a measurement error caused by the reaction between creatinine and the protein measurement indicator. Claim 2 recites the step of obtaining the first response value and that of the second response value, which use the first liquid system including the protein measurement indicator and the second liquid system free of the indicator, respectively. Depending on the methods used to obtain the first and second response values, which satisfy the above requirements, the step of calculating a protein concentration in the liquid sample by using the first and second response values may vary. Accordingly, this claim is clear and well defined, and this rejection should be withdrawn.

Claims 1-3, 5, 8, and 15-17 have been rejected under 35 U.S.C. 102(b) as being anticipated by Messenger et al. (European Patent No. 0909953). Applicants respectfully traverse this rejection.

In the step of obtaining a first response value in claim 2, the first response value that reflects a protein concentration and a reaction between creatinine and the protein measurement indicator is obtained. In the step of obtaining a second response value, the response value that reflects a creatinine concentration is obtained. Thus, in the method of claim 2, the first response value that reflects concentrations of both protein and creatinine and the second response value that reflects creatinine concentration are measured in separate steps, and in the step of calculating a protein concentration in the liquid sample, both first and second response values are used to eliminate a measurement error caused by creatinine that is included in the first liquid system and reacts with the protein measurement indicator.

In contrast, a method of Messenger is directed to a method to obtain the ratio of albumin concentration to creatinine concentration (albumin (mg)/creatinine (g)) of an

urine sample, which is known as a creatinine correction value in the art and is used to eliminate an effect of dilution or concentration of the urine sample (see para. [0005] on pages 2-3; see also, page 6, lines 7-19 of the specification). In the method of Messenger, an albumin concentration and a creatinine concentration are measured, and if the albumin concentration, i.e., an uncorrected concentration, obtained from the first analyte is within 30-300 mg/g, the ratio of albumin concentration to creatinine concentration (albumin (mg)/creatinine (g)) is calculated from the measured values of the first and second analytes (see para. [0007] on page 3 and para. [0010] on page 3). If the uncorrected albumin concentration in the first analyte is less than 30 mg/l or greater than 300 mg/l, the ratio of albumin concentration to creatinine concentration is 30 mg/g or 300 mg/l regardless of the measured values of creatinine concentrations in the second analyte (see para. [0008] on page 3 and para. [0012] on page 4). Thus, the reference discloses a method to correct the ratio of albumin concentration to creatinine concentration. Messenger, however, does not recognize the reaction between creatinine and the protein measurement indicator in the first liquid system, i.e., the first analyte, and thus does not recognize a step of obtaining a first response value that reflects a protein concentration in the first liquid system under influence of a reaction between the creatinine and the protein measurement indicator and the measurement error eliminated in the step of calculating a protein concentration in a liquid sample in claim 2. Consequently, the reference fails to disclose a step of calculating a protein concentration in the liquid sample by using the first and second response values for eliminating the measurement error caused by the reaction between creatinine and the protein measurement indicator. Accordingly, claim 2 and claims 3, 5, 8, and 15-17, which ultimately depend from claim 2, are distinguished from Messenger, and this rejection should be withdrawn.

Claims 4 and 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger et al. (European Patent No. 0909953). Applicants respectfully traverse this rejection.

Claims 4 and 6, which ultimately depend from claim 2, are distinguished from Messenger for at least the same reasons as discussed for claim 2 above. Accordingly, this rejection should be withdrawn.

Claims 7 and 11-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger et al. (European Patent No. 0909953) in view of Waheed et al. ("Mechanism of dye binding in the protein assay using eosin dyes", Anal. Biochem. 287, 73-79 (2000)). Applicants respectfully traverse this rejection.

Claims 7 and 11-13, which ultimately depend from claim 2, are distinguished from Messenger for at least the same reasons as discussed for claim 2 above.

Waheed discloses an assay of bovine serum albumin (BSA) (see abstract) but does not recognize a reaction between creatinine and an protein measurement indicator and thus does not recognize a step of obtaining a first response value that reflects a protein concentration in the first liquid system under influence of a reaction between creatinine and the protein measurement indicator and the measurement error eliminated in the step of calculating a protein concentration in a liquid sample of claims 7 and 11-13. Consequently, Waheed fails to disclose a step of calculating a protein concentration in a liquid sample by using the first and second response values for eliminating the measurement error caused by the reaction between creatinine and the protein measurement indicator as claims 7 and 11-13 recite. Accordingly, Waheed dose not remedy the deficiencies of Messenger, and this rejection should be withdrawn.

Claims 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Messenger et al. (European Patent No. 0909953) in view of Waheed et al. ("Mechanism of dye binding in the protein assay using eosin dyes", Anal. Biochem. 287, 73-79 (2000)) as described above, and further in view of Yip et al. (U.S. Patent No. 5,385,847). Applicants respectfully traverse this rejection.

Yip discloses a method for determination of urinary protein and creatinine in a single reaction vessel using a continuous process (see abstract). In Yip, an urine sample is treated in an order of steps such as first mixing with a reagent for measuring creatinine and determining a creatinine concentration in the sample and determining the creatinine concentration and second mixing with an antibody reagent for protein and determining a protein concentration or vice versa (see abstract and coln. 2, lines 48-64). The reference, however, does not recognize a reaction between creatinine and a protein measurement

indicator in the sample and thus does not recognize a step of obtaining a first response value that reflects a protein concentration in the first liquid system under influence of a reaction between creatinine and the protein measurement indicator and the measurement error eliminated in the step of calculating a protein concentration in a liquid sample of claims 9 and 10. Consequently, the reference fails to disclose a step of calculating a protein concentration in a liquid sample by using the first and second response values for eliminating a measurement error caused by the reaction between creatinine and the protein measurement indicator as claims 9 and 10 recites. Accordingly, Yip dose not remedy the deficiencies of Messenger, and this rejection should be withdrawn.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance.

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